

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

75 DEC 3 AID: 10

IN THE MATTER OF

The Dow Chemical Company &
Uniroyal Chemical, Division of
Uniroyal, Inc.,

Claimants

v.

The Ansul Company,

Respondent

FIFRA COMP. DOCKET NO. 50

Order

This matter has been held in abeyance pending the Administrator's decision on Claimant Dow's appeal in a related case (The Dow Chemical Company vs. Thompson-Hayward Chemical Company, FIFRA Comp. Docket No. 49) from a decision denying its motion for certification to the Administrator of an order denying Dow's motion for determination of Sec. 10(b) status of data relied upon in issuing Respondent's registration. On October 2, 1978, the Judicial Officer issued a decision in the cited case suspending the requirements of Sec. 2(c) and 2(d) of the Rules for a reasonable period of time to allow the Assistant Administrator for Toxic Substances to decide whether to issue a hearing notice under Sec. 6(b)(2) of the Act. If the Assistant Administrator decides not to issue such a hearing notice, the undersigned was directed to vacate the suspension upon notice of the decision. On the other hand, if a notice of hearing was issued, the suspension would

remain in effect until a final Agency decision in the Sec. 6(b)(2) proceeding. Inasmuch as Dow on March 29, 1978, filed a petition with the Administrator requesting that the registration at issue be cancelled the considerations cited by the Judicial Officer in FIFRA Comp. Docket No. 49 appear to be or should be applicable here. Accordingly, the requirements of Sec. 2(c) and 2(d) of the Rules are suspended for a reasonable period to enable a determination to be made as to whether to issue a notice of hearing under Sec. 6(b)(2). If such a notice is not issued the suspension will be lifted. However, if such a notice is issued the suspension will remain in effect pending final Agency decision in the Sec. 6(b)(2) proceeding.

There are presently pending:

- (1) Dow's motion, dated June 23, 1978, for a stay of proceedings pending a decision by the U. S. District Court for the Eastern District of Michigan on its action against the Administrator and Respondent, Ansul, filed June 21, 1978, which, inter alia, asks that the present proceeding be enjoined pending a determination of Sec. 10(b) status of the data and for an order declaring Respondent's registration null and void;
- (2) Ansul's motion, dated May 26, 1978, for certification to the Administrator under Rule 21(b) of an Order, dated May 16, 1978, denying in part its motion for an accelerated decision; and

- (3) The Registration Division's response to the undersigned's memorandum, dated March 21, 1978, which requested additional information pursuant to Sec. 2(g) of the Rules.


With respect to (1), the normal rule for the invocation of judicial remedies or relief requires that Administrative remedies be first exhausted. While in the cited action Dow alleges that all possible administrative remedies have been completely exhausted, suspending this proceeding pending the Court's decision would be the reverse of the usual procedure. Moreover, as pointed out in the letter opinion of March 21, 1978, granting the motion might have the effect of placing this matter on a suspense docket for many months or even years. Although Ansul supported Dow's motion for a stay until final resolution of the interlocutory appeal, Ansul has not supported the instant motion and is entitled to a reasonably prompt determination of its maximum liability, if any. The stay heretofore granted is considered the maximum reasonable. Accordingly, Dow's motion that the instant proceeding be stayed pending resolution of the mentioned action in the Eastern District of Michigan is denied.

Respecting (2), the requirements for certifying an interlocutory appeal to the Administrator (Sec. 21(b)) are that the order or ruling involves an important question of law or policy upon which there is a substantial ground for difference of opinion and either an immediate appeal from the order will materially advance the ultimate termination of the proceeding or review after the initial or accelerated decision is issued will be inadequate or ineffective. While it may well be that the

ruling of May 16, 1978, involves an important question of law or policy upon which there is substantial ground for difference of opinion, certifying the ruling on interlocutory appeal would materially advance the ultimate termination of the proceeding only if the Administrator agreed with Ansul's position that there is no right to compensation for data not specifically referenced by Ansul. In view of the equities favoring Claimants alluded to in the May 16 ruling, the Administrator is not likely to adopt Ansul's position even if he found Ansul's other arguments meritorious. Even if Ansul's position was ultimately upheld, Ansul would not thereby be prejudiced anymore than any other litigant whose motion for summary of judgment is denied and who must undertake the expense and inconvenience of a trial on the merits because of the rule against interlocutory appeals. Accordingly, Ansul's motion that the ruling of May 16, 1978, be certified to the Administrator on interlocutory appeal is denied.

Respecting (3), a copy of the Registration Division's reply dated May 12, 1978, to my memorandum of March 21, 1978, requesting additional information is enclosed.

Dated this 3rd day of October 1978.


Spencer T. Nissen
Administrative Law Judge

Enclosure

FIFRA COMP. Docket No. 49

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FIFRA COMP. Docket No. 50:

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DATE: MAY 12 1978

SUBJECT: Dow Chemical Company & Uniroyal Chemical, Division of Uni-
royal, Inc., Claimants v. The Ansul Company, Respondent
FIFRA Comp. Docket No. 50

FROM: Acting Director
for Registration Division (WH-567)

TO: The Honorable Spencer T. Nissen
Administrative Law Judge (A-110)

12 MAY 12 P2:03

In your March 21, 1978 memorandum you requested that we furnish additional information applicable to the subject proceeding. Our responses to your numbered requests are as follows:

1. You requested copies of any notes, memoranda or other documents relied upon in the reconstruction referred to in our January 6, 1978 memorandum.

Attached are the rough working notes of Richard C. Nelson (Attachment 1), the principal researcher in this reconstruction, which were relied upon. Also relied upon were the claim file already certified to your office and confidential data volumes of Dow, Uniroyal, and Ansul.

2. You requested that we submit a copy of Amendment to PPLF1075, Requesting Tolerance for Dinoseb (DNBP or 2 sec-butyl-4, 6-dinitrophenol) in food and forage crops, Vol. III.

This volume will be submitted to you shortly by our Freedom of Information Officer, Mr. Charles Colledge, per your instructions since we understand that Dow has claimed it as trade secret status.

- 3a. You requested that a copy of data on acute toxicity of Dow Technical Dinoseb on shrimp, crab and oysters be submitted to you, if not a part of Vol. VIII above.

These data are not a part of Volume VIII above and they will be submitted separately under the same conditions as Item 2 above.

- 3b. You requested that we indicate why the data on shrimp, crab and oysters were not relied on.

The shrimp, crab and oyster study in question is classified as a fish and wildlife study. Fish and wildlife data were not required at the time of the original registration of ANCRACK in 1971. Such data, though, sometimes aided us in reaching conclusions as to a pesticide's potentially adverse effects. In this case, however, concerns as to ANCRACK's adverse effects on fish and wildlife were already resolved before Dow submitted their study on shrimp, crabs, and oysters. Registration Division, in a letter to Ansul dated November 1, 1972 (Attachment 2), requested amplification in the fish and wildlife precautionary statements on ANCRACK's label which resolved our concerns as to ANCRACK's adverse effects on fish and wildlife. Dow's study was submitted May 2, 1973 to support several of their DNBPs registrations. The Ansul precautionary labeling did not change as a result of accepting the Ansul tank mix amendment. It is our reconstruction thus that this Dow fish and wildlife study cannot be construed as having been relied on for the acceptance of the tank mix amendment.

- 4a. You requested that we indicate the submission dates of toxicology data for several Dow products. This information is tabled below:

<u>Dated Data Submitted</u>	<u>Supporting Registration No.</u>
April 4, 1966	464-10
	464-98
	464-146
November 23, 1970	464-10
November 23, 1970	464-98
April 9, 1963	464-98

- 4b. You requested that we furnish a statement as to why it was unnecessary to rely on those data cited in Item 4a that were submitted after January 1, 1970.

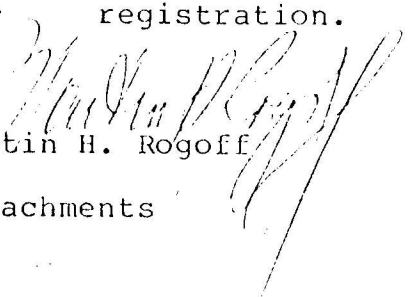
The precautionary labeling on ANCRACK's label was established before Ansul applied for the ANCRACK-SUFLAN tank mix amendment and it did not change as a result of accepting this amendment. There was not a requirement for additional safety data to support a tank-mix (mixed in the field) label amendment.

- 4c. You requested that we furnish a statement as to why it was not necessary to rely on the document designated PP1F1075, November, 1970.

This "document" is actually seven volumes of a Dow Pesticide Petition. To the best of our knowledge and based on our computer records none of these volumes contained environmental chemistry data on DNBP and naphthalam, which, as stated in our January 6, 1978 memo, were required to support the subject tank mix amendment in addition to Elanco's referenced data. Thus, it is our reconstruction that none of the seven volumes of PP1F1075 submitted in November, 1970 were relied on in issuing the amended registration of ANCRACK.

5. You requested that we furnish an explanation as to why no reliance was placed on Dow residue data, if any, which were submitted after January 1, 1970.

There were Dow residue data submitted after January 1, 1970. Residue data is associated with application rates on the registered label. However, the ANCRACK application rates for the subject tank mix were already on ANCRACK's label at the time the tank mix application was submitted and no further data review was necessary. It is thus our reconstruction that no additional review of residue data was needed to accept the amended registration.


Martin H. Rogoff

Attachments

#50: Lucas to Don, Unisys

Conversation with B. Taylor 12/8/77:
required data: for tank mix

eff. }
phytox. } mix
stab. }
residue }

as prod. reference

Elamo
if include Pyraz + Inflan
data (did themselves, & if
not should have registered)

in dbt -
(C) if Elamo didn't do all
required studies

ask
Harcourt: What were data requirements for
tank mix @ 3/30/76
more than efficacy & residue? ^{phytox}
(done by Elamo)

Adams: 12/9/77

- ① Eff. + Phytotox. & Residue
- ② Env. Chem

residue only
if residues of
A. i. in mix are
dif. from that for
2 sep products

So: Efficiency and En fate needed
(residue no, because application
rates were the same)

1. Efficiency of Elanco (12/22/72) ad-
equates (Dyngop + Surflan)

2. En fate: Elanco data is only
on Surflan (petition for soybeans) →

→ ∴ only data needed is D En
fate for Dyngop (or DNBP +
Alamop)

Since this data was not referenced
or submitted by Ansel this amendment
was partially in effect 2c. i.e.
PM reg. amended label on basis of previous
knowledge of DNBP and Alamop.

Need data from Univoxyl and Dow:

Univoxyl ⁰⁰³¹⁵¹ ⁰⁹⁸³ ^{residue} En fate - 2-16-70
Residue for En - 7-30-70 ^{no final} ¹²⁰⁵⁰¹ → check value list of K. Simon Requests
En fate 2-14-75

And must decide which of above was
relied upon to register Ansel

Sub. DATE	ACC. #	Co.	DATA TYPE
4-9-73	090733	Dow	En. Fate DNBP
2-16-70	003261	Uniqval	EFF. & RESIDUES-DYANAP ✓
00326	no record in TSD	"	RESIDUES, F+W, RESIDUES
7-30-70			
2-14-75	120302	"	En. FATE - PLANAP ✓

1. 4/8/76 - Amend appl. for amended registration to add AnCrak - Sunfla tank mix to label
a) 2(b) MOS
b) Elanco letter enclosed authorizes use of Elanco data

2. FR notice 8/30/76
Don claim rec'd - 6/30/76 Univoxl-51

3. Amendment accepted 8/20/76 / after label submitted 8/5/76

4. Data needed for ^{tank mix} registration?
a) Eff. + phytotox.
b) Env. fate.

5. Elanco data (referenced by appl.):
a) Efficacy on Sunflan + Dynamap
b) Env. fate on Sunflan only

6. Env. fate data on DNBP + Alamp are covered in:
a) Univoxl volume (sub. 2-14-75) - '1
b) Don volume (sub. 2-14-75) - Alamp
4-9-73 DNBP.

∴ Appl. processed as partial 2(c) application indirectly relying on Don and Univoxl data

#50: Incrash is Down, Unmixed

Conversation with B. Taylor 12/8/77
required data: for tank mix

eff.
Phytotox. } mix
stab. }
residue }

see past reference

Elanco
if include Pyraz + Inflan
data (did themselves, ok if
not should have registered)

indef.
(C) if Elanco didn't do all
required studies

ask
Elanco: What were data requirements for
tank mix @ 3/30/76
more than efficacy & residue?
(usually by Elanco)

Adm. 12/9/77

- ① Eff. + Phytotox. & Residue
- ② Env. Chem

residue on
if residues &
A. i. in mix
dif from the
2 sep prodn.

NOV 1 1972

The Ansul Company
Attention: Roy Olson
One Stanton Street
Marinette, Wisconsin 54143

Compliments:

Subject : AMCEACK 2
EPA Reg. No. 6303-73
Your application of September 14, 1972

The labeling referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable, and a stamped copy is enclosed for your records.

1. Correct the chemical in the ingredient statement to read as follows: dimesab, sodium salt (sodium 2-soc-butyl-4,6-dinitrobenzoate)
2. Delete the statement, "Do not take internally". The word "Poison" must appear on the label in red on a contrasting background.
3. We are updating our environmental cautions therefore, modify the statement "Keep out of any body... on this label" to read as follows:
This product is toxic to fish., Birds and other wildlife in treated areas may be killed.; Keep out of lakes, streams, or ponds.; Do not apply where runoff is likely to occur.; Do not apply when weather conditions favor drift from areas treated.; Do not contaminate water by cleaning of equipment or disposal of wastes.; and Apply this product only as specified on this label."

Sincerely,

T. E. Adanczyk
Chief
Fungicide-Herbicide Branch

Enclosure
Stamped label

EPA:PP-PH:ldi 10-31-72

52575